AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE	PAGE OF PAGES
	1 2

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. *(If applicable)*
002	See Block 16C		C.2.1.3.01

6. ISSUED BY CODE CPOD

CPOD
US Environmental Protection Agency
26 West Martin Luther King Drive
Mail Code: NWD
Cincinnati OH 45268

7. ADMINISTERED BY *(If other than Item 6)* CODE

8. NAME AND ADDRESS OF CONTRACTOR *(No., street, county, State and ZIP Code)*

BATTELLE MEMORIAL INSTITUTE
505 KING AVE
COLUMBUS OH 432012693

CODE (b)(4) FACILITY CODE

(x) 9A. AMENDMENT OF SOLICITATION NO.

9B. DATED *(SEE ITEM 11)*

x 10A. MODIFICATION OF CONTRACT/ORDER NO. EP-C-11-038
0004

10B. DATED *(SEE ITEM 13)* 08/06/2012

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

☐ The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers ☐ is extended, ☐ is not extended.
Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA *(If required)*
See Schedule

13. THIS ITEM ONLY APPLIES TO MODIFICATION OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

CHECK ONE	
	A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: *(Specify authority)* THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.
	B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES *(such as changes in paying office, appropriation date, etc.)* SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).
	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:
X	D. OTHER *(Specify type of modification and authority)* Mutual Agreement between the Parties and Battelle's letter dated April 4, 2014

E. IMPORTANT: Contractor ☒ is not, ☐ is required to sign this document and return _____ copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION *(Organized by UCF section headings, including solicitation/contract subject matter where feasible.)*

DUNS Number: (b)(4)
The purpose of this modification is to extend the period of performance for an additional two (2) months through June 9, 2014. This is a No Cost extension.
TOPO: Joseph Wood
Delivery: 30 Days After Award
Delivery Location Code: ORD NHSRC DCMD
US Environmental Protection Agency
US EPA
4930 Old Page Road
Room #: E311G
Durham NC 27703 USA
Continued ...

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER *(Type or print)*	16A. NAME AND TITLE OF CONTRACTING OFFICER *(Type or print)*
	Camille W. Davis

15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B.	16C. DATE SIGNED
(Signature of person authorized to sign)		Camille W. Davis ELECTRONIC SIGNATURE	04/07/2014

NAME OF OFFEROR OR CONTRACTOR
BATTELLE MEMORIAL INSTITUTE

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	Payment: RTP Finance Center US Environmental Protection Agency RTP-Finance Center (D143-02) 109 TW Alexander Drive Durham NC 27711 FOB: Destination Period of Performance: 08/06/2012 to 06/09/2014				

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE	PAGE OF PAGES
	1 | 2

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. *(If applicable)*
001	See Block 16C	PR-ORD-12-01943	C.2.1.3.01

6. ISSUED BY CODE CPOD

CPOD
US Environmental Protection Agency
26 West Martin Luther King Drive
Mail Code: NWD
Cincinnati OH 45268

7. ADMINISTERED BY *(If other than Item 6)* CODE

8. NAME AND ADDRESS OF CONTRACTOR *(No., street, county, State and ZIP Code)*

BATTELLE MEMORIAL INSTITUTE
505 KING AVE
COLUMBUS OH 432012693

CODE (b)(4) FACILITY CODE

(x) 9A. AMENDMENT OF SOLICITATION NO.

9B. DATED *(SEE ITEM 11)*

x 10A. MODIFICATION OF CONTRACT/ORDER NO. EP-C-11-038
0004

10B. DATED *(SEE ITEM 13)* 08/06/2012

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

☐ The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers ☐ is extended, ☐ is not extended.
Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA *(If required)*
See Schedule

13. THIS ITEM ONLY APPLIES TO MODIFICATION OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

CHECK ONE	
	A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: *(Specify authority)* THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.
	B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES *(such as changes in paying office, appropriation date, etc.)* SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).
	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:
X	D. OTHER *(Specify type of modification and authority)* Mutual Agreement between the Parties and Battelle's letter dated December 19, 2013

E. IMPORTANT: Contractor ☒ is not, ☐ is required to sign this document and return _____ copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION *(Organized by UCF section headings, including solicitation/contract subject matter where feasible.)*

DUNS Number: (b)(4)
The purpose of this modification is to extend the period of performance for an additional two (2) months through April 7, 2014. This is a No Cost extension.
TOPO: Joseph Wood
LIST OF CHANGES:
Reason for Modification : No Cost Extension

Period Of Performance End Date changed
From: 02-06-2014
To: 04-07-2014

Continued ...

Except as provided herein, all terms and conditions of the document referenced in item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER *(Type or print)*		16A. NAME AND TITLE OF CONTRACTING OFFICER *(Type or print)*	
		Camille W. Davis	
15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA	16C. DATE SIGNED
_____ *(Signature of person authorized to sign)*		_____ *(Signature of Contracting Officer)*	12/20/2013

NAME OF OFFEROR OR CONTRACTOR
BATTELLE MEMORIAL INSTITUTE

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	CHANGES FOR LINE ITEM NUMBER: 1 End Date changed From: February 6, 2014 To: April 7, 2014 This is a No Cost extension. Delivery: 30 Days After Award Delivery Location Code: ORD NHSRC DCMD US Environmental Protection Agency US EPA 4930 Old Page Road Room #: E311G Durham NC 27703 USA Payment: RTP Finance Center US Environmental Protection Agency RTP-Finance Center (D143-02) 109 TW Alexander Drive Durham NC 27711 FOB: Destination Period of Performance: 08/06/2012 to 04/07/2014				

ORDER FOR SUPPLIES OR SERVICES

PAGE OF PAGES: 1 of 17

IMPORTANT: Mark all packages and papers with contract and/or order numbers.

1. DATE OF ORDER: 08/06/2012	2. CONTRACT NO. (If any): EP-C-11-038
3. ORDER NO.: 0004	4. REQUISITION/REFERENCE NO.: PR-ORD-12-01943

5. ISSUING OFFICE (Address correspondence to):
CPOD
US Environmental Protection Agency
26 West Martin Luther King Drive
Mail Code: NWD
Cincinnati OH 45268

6. SHIP TO:
a. NAME OF CONSIGNEE: US Environmental Protection Agency
b. STREET ADDRESS: US EPA
4930 Old Page Road
Room #: E311G
c. CITY: Durham
d. STATE: NC
e. ZIP CODE: 27703

7. TO:
a. NAME OF CONTRACTOR: BATTELLE MEMORIAL INSTITUTE
b. COMPANY NAME:
c. STREET ADDRESS: 505 KING AVE
d. CITY: COLUMBUS
e. STATE: OH
f. ZIP CODE: 432012693

f. SHIP VIA:

8. TYPE OF ORDER
☐ a. PURCHASE
REFERENCE YOUR:
Please furnish the following on the terms and conditions specified on both sides of this order and on the attached sheet, if any, including delivery as indicated.
☒ b. DELIVERY
Except for billing instructions on the reverse, this delivery order is subject to instructions contained on this side only of this form and is issued subject to the terms and conditions of the above-numbered contract.

9. ACCOUNTING AND APPROPRIATION DATA: See Schedule

10. REQUISITIONING OFFICE: CPOD

11. BUSINESS CLASSIFICATION (Check appropriate box(es))
☐ a. SMALL ☒ b. OTHER THAN SMALL ☐ c. DISADVANTAGED ☐ d. WOMEN-OWNED ☐ e. HUBZone
☐ f. SERVICE-DISABLED VETERAN-OWNED ☐ g. WOMEN-OWNED SMALL BUSINESS (WOSB) ELIGIBLE UNDER THE WOSB PROGRAM ☐ h. EDWOSB

12. F.O.B. POINT: Destination

13. PLACE OF		14. GOVERNMENT B/L NO.	15. DELIVER TO F.O.B. POINT ON OR BEFORE (Date)	16. DISCOUNT TERMS
a. INSPECTION	b. ACCEPTANCE			
Destination	Destination		30 Days After Award	

17. SCHEDULE (See reverse for Rejections)

ITEM NO. (a)	SUPPLIES OR SERVICES (b)	QUANTITY ORDERED (c)	UNIT (d)	UNIT PRICE (e)	AMOUNT (f)	QUANTITY ACCEPTED (g)
	DUNS Number: (b)(4) TOPO: Joseph Wood Continued ...					

18. SHIPPING POINT:
19. GROSS SHIPPING WEIGHT:
20. INVOICE NO.:
17(h) TOTAL (Cont. pages): $0.00

21. MAIL INVOICE TO:
a. NAME: RTP Finance Center
SEE BILLING INSTRUCTIONS ON REVERSE
b. STREET ADDRESS (or P.O. Box): US Environmental Protection Agency
RTP-Finance Center (D143-02)
109 TW Alexander Drive
c. CITY: Durham
d. STATE: NC
e. ZIP CODE: 27711
17(i) GRAND TOTAL: $180,666.00

22. UNITED STATES OF AMERICA BY (Signature):

23. NAME (Typed): Camille W. Davis
TITLE: CONTRACTING/ORDERING OFFICER

IMPORTANT: Mark all packages and papers with contract and/or order numbers.

DATE OF ORDER	CONTRACT NO.	ORDER NO.
08/06/2012	EP-C-11-038	0004

ITEM NO. (a)	SUPPLIES/SERVICES (b)	QUANTITY ORDERED (c)	UNIT (d)	UNIT PRICE (e)	AMOUNT (f)	QUANTITY ACCEPTED (g)
	Admin Office: CPOD US Environmental Protection Agency 26 West Martin Luther King Drive Mail Code: NWD Cincinnati OH 45268 Period of Performance: 08/06/2012 to 02/06/2014					
0001	SOW under STREAMS2 contract Award Type: Cost-plus-fixed-fee Total Estimated Cost: $ (b)(4) Fixed Fee: $ (b)(4) Completion Form Accounting Info: 11-12-C-264B000-404F72APC-2532-12264BE044-001 BFY: 11 EFY: 12 Fund: C Budget Org: 264B000 Program (PRC): 404F72APC Budget (BOC): 2532 DCN - Line ID: 12264BE044-001 Funding Flag: Partial Funded: $62,900.00 Accounting Info: 12-13-C-264B000-401F72XPC-2532-12264BE044-002 BFY: 12 EFY: 13 Fund: C Budget Org: 264B000 Program (PRC): 401F72XPC Budget (BOC): 2532 DCN - Line ID: 12264BE044-002 Funding Flag: Partial Funded: $117,766.00 The obligated amount of award: $180,666.00. The total for this award is					

TOTAL CARRIED FORWARD TO 1ST PAGE (ITEM 17(H))	$0.00

PERFORMANCE WORK STATEMENT

PERSISTENCE OF VEGETATIVE BACILLUS ANTHRACIS AND YERSINIA PESTIS

OMIS C.2.1.3

TABLE OF CONTENTS

TITLE

Persistence of Vegetative *Bacillus anthracis* and *Yersinia pestis*

I. ESTIMATED PERIOD OF PERFORMANCE

The estimated period of performance shall be 18 months from the date of award.

II. SUMMARY OF OBJECTIVES

This work shall provide data on how long *Bacillus anthracis* (as vegetative cells, not spores) survives on different materials, with and without exposure to simulated sunlight (ultraviolet light in the A and B range; referred to as UV-A/B). The same tests shall also be conducted with *Yersinia pestis*. Previous tests have been conducted to determine persistence of *B. anthracis* subject to simulated sunlight, but with *B. anthracis* in spore form. Refer to EPA report EPA/600/R-10/048, May 2010. Also, previous tests have been conducted to assess persistence of *Y. pestis*, but these tests did not use UV-A/B; refer to report EPA/600/R-10/086, August 2010.

III. RELEVANCE

The results of these tests will provide information about how long *B. anthracis* may survive outdoors when exposed to simulated sunlight, when in vegetative cell form. (Development of germinants to convert dormant *B. anthracis* spores into vegetative cells, so that chemical inactivation is easier and persistence is diminished, is currently being investigated under separate research projects.) This information will be useful in determining the conditions in which decontamination may or may not be necessary. Similar information is needed for *Y. pestis*.

IV. BACKGROUND

The U.S. Environmental Protection Agency (EPA) has the responsibility for protecting human health and the environment from accidental and intentional releases of hazardous and toxic materials. According to Homeland Security Presidential Directive 10 (HSPD-10), the EPA is tasked with developing strategies, guidelines, and plans for decontamination of persons, equipment, and facilities following a biological weapons attack. In response to this directive, the EPA Office of Research and Development (ORD) National Homeland Security Research Center's (NHSRC) Decontamination and Consequence Management Division (DCMD) is conducting persistence studies of *B. anthracis* (Ames strain) and other biological agents on materials/surfaces. This work will utilize methods from previous persistence and decontamination studies that have already been conducted by DCMD.

V. SCOPE

The purpose of the study is to quantify the recovery of *B. anthracis* and *Y. pestis* vegetative cells from 4 materials with and without exposure to artificial sunlight. The materials will be topsoil, unpainted concrete, bare pine wood, and glass. Four separate tests (4 test durations) at laboratory ambient conditions shall be conducted. Sufficient replicates, blanks, and positive controls shall be used, consistent with standard microbiological and quality assurance procedures, and past work conducted by DCMD (see references noted below).

Conference calls shall be established on an *ad hoc* basis between the EPA TOCOR and the contractor. During these conference calls the contractor shall report on progress made in the project and any technical issues encountered in implementation of the test plan.

VI. TECHNICAL APPROACH

For each test, the effort shall include the recovery of viable agent from each material before (positive control) and after each test duration has been completed. Five replicates for each agent-material-time point combination and five replicates for each agent material positive control shall be included in each experiment. Test and analytical methods shall be adopted from past or on-going efforts, in consultation with the TOCOR.

VII. TASKS

TASK 1: DRAFT A QUALITY ASSURANCE PROJECT PLAN.
The contractor shall draft a Quality Assurance Project Plan (QAPP) that shall cover the work outlined in this performance work statement (PWS) including a project timeline. This QAPP shall follow guidelines set forth in Attachment #1 to the PWS. In this plan, the test matrices must include laboratory blanks, positive controls, and procedural blanks in addition to the test coupons. The QAPP shall be submitted to the EPA TOCOR within 30 days of award, and then revised per TOCOR and the EPA QA Manager comments. No tests shall be conducted until the QAPP has been approved by the EPA QA manager. (All approvals will come over email.) Approval time is usually 2-3 weeks.

All methods, materials, procedures, equipment, microbiological preparations and analyses, etc., conducted under this task order, shall be consistent with those used in previous related studies directed by DCMD, and as documented in the following reports and journal articles, unless otherwise directed by the TOCOR:

- Investigation of Simulated Sunlight in the Inactivation of *B. anthracis* and *B. subtilis* on Outdoor Materials. EPA/600/R-10/048, May 2010. (For methods related to the UV-A/B source and measurement, *B. anthracis*, coupon materials)
- Persistence Testing and Evaluation of Fumigation Technologies for Decontamination of Building Materials Contaminated with Biological Agents. EPA/600/R-10/086, August 2010. (For methods related to persistence tests with *Y. pestis*.)

- Calfee, M.W. and Wendling, M. Inactivation of Vegetative Bacterial Threat Agents on Environmental Surfaces. In preparation; available upon request. (For additional information on microbiological procedures using *Y. pestis.*)
- Calfee, M.W. and Wendling, M. The effects of environmental conditions on persistence and inactivation of *Brucella suis* on building material surfaces. Letters in Applied Microbiology, doi:10.1111/j.1472-765X.2012.03237.x (For information related to maintaining and measuring temperature and relative humidity, and persistence tests in general.)

TASK 2: PERFORM PERSISTENCE TESTS.

The contractor shall conduct experiments to determine the recovery of *B. anthracis* vegetative cells (Ames strain) on 4 materials at 4 non-zero time points (i.e., four separate tests), at 22 ± 2 °C and relative humidity of 40% ± 15. The materials shall be topsoil, unpainted concrete, glass, and bare pine wood. Tests shall be conducted with and without UV-A/B exposure, for a total of 8 separate experiments. Initial test durations shall be selected (based on whether UV-A/B will be present or not) in consultation with the TOCOR during the writing of the QAPP, and follow on test durations shall be selected based on results of ongoing tests. It is expected that the longest durations tested may be between 2-3 months.

The same matrix of tests shall also be conducted with *Y. pestis*. If feasible, tests with *Y. pestis* and *B. anthracis* can occur simultaneously in the same test chamber. However, if initial test results show a significant difference (based on judgement of TOCOR) in persistence results between the two microbes, separate tests shall be conducted.

Five replicate agent-material test coupons and 5 replicate agent-material positive controls shall be included in each experiment, with a sufficient number of blanks.

Inactivation of the agents over time shall be determined quantitatively (i.e., log reduction) based on the recovery of the agent from the tested coupons and on the positive controls, as described in more detail in the QAPP, The log reduction results shall be reported in terms of each time point as well as UV dose.

Prior to the persistence testing, preliminary tests shall be conducted to determine and characterize the UV-A and UV-B levels as a function of location within the test chamber, and if there is any reduction in intensity over time. Similar preliminary tests shall be conducted to ensure temperature and RH can be maintained in the appropriate range with and without UV-A/B.

One separate test shall be conducted to assess the effect of higher levels of UV-A. This test shall be conducted with one material, one test duration, and with *Y. pestis* and *B. anthracis* vegetative cells. It is expected that in addition to the UV-A/B source used for the tests described previously in this task, a separate, additional UV-A source will be used for this separate experiment.

TASK 3: REPORT

The contractor shall prepare three drafts of the report. The first draft of the report shall be received by the TOCOR no later than 3 weeks after completion of the final test. The EPA TOCOR will provide comments on the first draft within 2 weeks of receipt, and the contractor shall revise the report based on the TOCOR comments within 1 week of receiving the TOCOR comments. The TOCOR will send the second draft of the report for peer and QA review (which may take 3 weeks), and then submit the peer and QA comments to the contractor. The contractor shall revise the report (prepare the third draft) based on the comments from the peer and QA reviewers, and in consultation with the TOCOR, no later than the final date of this TO.

VIII. DELIVERABLE SCHEDULE

1. On a monthly basis for the duration of the project, the contractor shall submit, in electronic format, progress reports summarizing technical progress, problems encountered, monthly and cumulative financial expenditures, and cost and schedule variance.

3. Within 1 month of the issuance of this contract, the QAPP shall be provided to the EPA, in electronic format (Microsoft Word). The EPA TOCOR shall then coordinate EPA QA review of the QAPP. The contractor shall then address any comments resulting from these reviews within 10 days of receipt of the comments. The contractor shall then provide a final copy of the QAPP in electronic format. Work covered in this PWS shall not begin until the QAPP has been approved by the EPA Quality Assurance Manager. The QAPP shall contain work plans detailing how the experiments shall be run and include a timetable for task completion. The awardee shall adhere to QA requirements as delineated in "Attachment #1" to this PWS.

4. Transfer of project data (including raw data) shall occur at the conclusion of each experiment within each task. The data sheets shall also include the experimental conditions (e.g. temperature and relative humidity, and UV-A/B levels), the measured agent levels on all of the coupons (test coupons, procedural blanks, positive controls, and laboratory blanks), etc.. The subsequent experiments shall not begin until the EPA TOCOR has reviewed and approved the data (1-2 days from receipt of data) from the current task.

5. The first draft of the report shall be submitted no later than 8 weeks prior to the completion of this task order. The second draft of the report shall be submitted within 1 week of receiving comments from the TOCOR. The third draft of the report shall be submitted within 1 week after receiving peer and QA review comments and consulting with TOCOR about how to address changes in report.

7. A document describing any deviations from the QA plan shall also be provided along with the final report.

Table 1. Deliverable schedule

Task Number	Deliverable	Due Date
1	Draft QAPP (in Microsoft Word)	Within 30 days from award of task order.
1	QAPP (in Microsoft Word) with TOCOR and QA comments incorporated.	Within 10 days of receipt of TOCOR and QA comments.
2	Project data and experimental conditions. (Excel spreadsheets)	Within 2 days of completing experiment and all plate data have been counted and tabulated.
3	Report drafts (in Microsoft Word)	The first draft of the report shall be submitted no later than 8 weeks prior to completion of this task order. The second draft of the report shall be submitted within 1 week of receiving comments from the TOCOR. The third draft of the report shall be submitted within 1 week after receiving peer and QA review comments and consulting with TOCOR about how to address changes in report.

IX. REPORTING REQUIREMENTS

1. Laboratory data shall be transferred electronically to the EPA TOCOR after the conclusion of each trial or series of tests. All products developed under this PWS (e.g., the above mentioned technical report) must conform to the requirements of EPA/NHSRC's guide to writing research reports found here:

   http://www.epa.gov/nhsrc/pubs/FINAL_PDF_Policy_and_Guidance.pdf

2. Prior to submission of the final data package all of the data shall be given to the EPA TOCOR in electronic format (specifically Microsoft Excel spreadsheets). The data on these spreadsheets shall be straightforward and explanation of the results via comments shall be added if they are not straightforward.

3. Copies of internal audit reports and responses shall be sent to the EPA TOCOR in a timely fashion. The TOCOR and EPA Quality Assurance Manager shall be immediately notified of any critical findings.

4. The contractor shall document all data analysis including statistical models and related assumptions.

X. QUALITY ASSURANCE

The awardee shall comply with all requirements as delineated on the "Quality Assurance Planning Requirements Form (QARF)" included with this extramural action; see attachment #1 and #2. The contractor shall prepare a QAPP in accordance with http://www.epa.gov/quality/qs-docs/r5-final.pdf. For guidance on preparing a research-specific QAPP, the preparer should refer to the project specific requirements provided in NHSRC's QMP. The QAPP shall be approved prior to the start of any laboratory work. Additional information related to QA requirements can be found at www.epa.gov/quality.

NHSRC QUALITY ASSURANCE REQUIREMENTS FORM
Attachment 1 to the Statement of Work

I GENERAL INFORMATION

Title:	Persistence of Vegetative Bacillus anthracis and Yersinia pestis	
Description:	Study to determine persistence of anthrax in vegetative state, plus Y. pestis	
Project ID:	C.2.1.3.01	
Status:	Original	
Number Ammended:		
QA Category:	III	
Action Type:	Extramural	
Peer Review Category:	III	
Security Classification:	Unclassified	
Project Type:	Applied Research	
QAPP Status 1:	Not Delivered	
Vehicle Status:	Existing Vehicle	
Vehicle Type:	Vehicle Number:	STREAMS2
	Work Assignment Number:	N/A
	Delivery/Task Order Number:	unknown
	Modification Number:	N/A
	Other:	N/A

*If you are processing an **IAG or CRADA**, the responsibility for QA must be negotiated within the agreement. The TLPs in consultation with the QAMs in the various organizations must agree on, and document, which organization will take the lead for QA, the names of the QAM and TLP from each organization, and the QA requirements that will be adhered to during the agreement. Include this info in the IAG/CRADA package.*

II SCOPE OF WORK

Yes — Does the Statement of Work contain the appropriate QA language?

The awardee shall comply with all requirements as delineated on the "Quality Assurance Planning Requirements Form (QARF)" included with this extramural action. The contractor shall prepare a QAPP in accordance with the R-2 and R-5 and/or the attachments provided with the SOW. The QAPP must be approved prior to the start of any work. Additional information related to QA requirements can be found at http://www.epa.gov/quality/qs-docs/r5-final.pdf

Yes — Does this extramural action involve the collection, generation, use, and/or reporting of environmental data; the design, construction, and operation of environmental technologies; or development of software, models, or methods?
(If "No" then skip to Section IV, and sign the form.)

No — Will the SOW or any subsequent work assignments or task orders involve any cross-organizational efforts within EPA?

No — Has a QAPP already been approved for the activities specified in the SOW?

No — Is an applicable QAPP in the process of being prepared, revised, or approved by EPA personnel for future use

by the contractor? (QA approval must be obtained before the contractor can start work.)

III QA DOCUMENTATION OPTIONS

All documentation specified under "Other" must be defined in the NHSRC Quality Management Plan and be consistent with requirements defined in EPA Manual 5360 A1. For all items checked below, there must be adequate information in the SOW (or its appendices) for the offeror to develop this documentation. Where applicable, reference a specific section of the SOW. *(R-2 refers to EPA Requirements for Quality Management Plans (QA/R-2) (EPA/240/B-01/002, 03/20/01) and R-5 refers to EPA Requirements for Quality Assurance Project Plans (QA/R-5) (EPA/240/B-01/003, 03/20/01). Copies of these documents are available at http://www.epa.gov/quality/qa_docs.html.)*

After Award Documentation

R2	Documentation of an organization's Quality System. QMP developed in accordance with:
R2 and R5	Combined documentation of an organization's Quality System and application of QA and QC to the single project covered by the contract: Developed in accordance with:
R5	Documentation of the application of QA and QC activities to applicable project(s). Developed in accordance with:
This SOW	Programmatic QA Project Plan with supplements for each specific project, developed in accordance with:
Not Applicable	Existing documentation of the application of QA and QC activities will be used:

IV SIGNATURE BLOCK

The signatures below verify that the Statement of Work (SOW) has been reviewed to ascertain the necessary QA and QC activities required to comply with EPA Order 5360.1 A2, that the COR understands these requirements, and that the COR will ensure that the quality requirements indicated on the previous pages of this form are incorporated into all associated SOWs. *(Sign/date below, obtain a concurrence signature from the QA Staff, and submit the form along with the other extramural action documentation.)*

Joe Wood NHSRC-DCMD Technical Lead Person	05/02/2012 Date	Eletha Roberts NHSRC-DCMD QA Staff Member	05/02/2012 5/10/2012 Date

QAPP REQUIREMENTS FOR APPLIED RESEARCH PROJECTS
(from Appendix B of the NHSRC QMP)

An applied research project is a study to demonstrate the performance of technologies under defined conditions. These studies are often pilot- or field-scale. The following requirements should be addressed as applicable.

SECTION 0.0, APPROVAL BY PROJECT PARTICIPANTS

The EPA Technical Lead Person (TLP) shall be responsible for obtaining signatures of appropriate project participants on the signature page of the QA plan, documenting agreement to project objectives and the approach for evaluating these objectives.

A distribution list shall be provided to facilitate the distribution of the most recent current version of the QAPP to all the principal project participants.

SECTION 1.0, PROJECT DESCRIPTION AND OBJECTIVES

1.1 The purpose of study shall be clearly stated.

1.2 The process, site, facility, and/or environmental system to be tested shall be described.

1.3 Project objectives shall be clearly stated and identified as primary or non-primary.

SECTION 2.0, PROJECT ORGANIZATION

2.1 Key points of contact for each organization involved in the project shall be identified.

2.2 All QA Managers and their relationship in the organizations (*i.e.*, location within each organization) shall be identified with evidence that the QA Manager is independent of project management.

2.3 Responsibilities of all other project participants and their relationship to other project participants shall be identified, meaning that organizations responsible for planning, coordination, sample collection, sample custody, measurements (*i.e.*, analytical, physical, and process), data reduction, data validation, and report preparation shall be clearly identified.

SECTION 3.0, EXPERIMENTAL APPROACH

3.1 The general approach and the test conditions for each experimental phase shall be provided. The statistical methods that will be used to evaluate the data (*i.e.*, ANOVA, or summary statistics) should be identified.

(NOTE: As deemed appropriate to the project by the TLP, the information requested in Sections 3.2, 3.3, and 3.4 may be presented here or in Section 4; the information requested in Sections 3.5 may be presented here or in Section 5; and the information requested in Sections 3.6 may be presented here or in Section 7.)

3.2 The sampling strategy shall be included and evidence must be presented to demonstrate that the strategy is appropriate for meeting primary project objectives, *i.e.*, a description of the statistical method or scientific rationale used to select sample sites and number of samples shall be provided.

3.3 Sampling/monitoring points for all measurements (*i.e.*, including locations and access points) shall be identified.

3.4 The frequency of sampling/monitoring events, as well as the numbers for each sample type and/or location shall be provided, including QC and reserve samples.

3.5 All measurements (*i.e.*, analytical [chemical, microbiological, assays], physical, and process) shall be identified for each sample type or process, and project-specific target analytes shall be listed and classified as critical or noncritical in the QAPP.

3.6 The planned approach (statistical and/or non-statistical) for evaluating project objectives shall be included.

SECTION 4.0, SAMPLING PROCEDURES

4.1 Whenever applicable, the method used to establish steady-state conditions shall be described.

4.2 Known site_specific factors that may affect sampling/monitoring procedures shall be described.

4.3 Any site preparation needed prior to sampling/monitoring shall be described.

4.4 Each sampling/monitoring procedure to be used shall be discussed or referenced. If compositing or splitting samples, those procedures shall be described.

4.5 For samples requiring a split sample for either QA/QC purposes or for shipment to a different laboratory, the QAPP shall identify who is responsible for splitting samples, and where the splitting is performed (*e.g.*, field versus lab).

4.6 If sampling/monitoring equipment is used to collect critical measurement data (*i.e.*, used to calculate the final concentration of a critical parameter), the QAPP shall describe how the sampling equipment is calibrated, the frequency at which it is calibrated, and the acceptance criteria for calibration or calibration verification, as appropriate.

4.7 If sampling/monitoring equipment is used to collect critical measurement data, the QAPP shall describe how cross-contamination between samples is avoided.

4.8 The QAPP shall include a discussion of the procedures to be used to assure that representative samples are collected.

4.9 A list of sample quantities to be collected, and the sample amount required for each analysis, including QC sample analysis, shall be specified.

4.10 Containers used for sample collection, transport, and storage for each sample type shall be described.

4.11 Describe how samples are uniquely identified.

4.12 Sample preservation methods (*e.g.*, refrigeration, acidification, *etc.*), including specific reagents, equipment, and supplies

required for sample preservation shall be described.

4.13 Holding time requirements shall be noted.

4.14 Procedures for packing and shipping samples shall be described.

4.15 Procedures to maintain chain_of_custody (*e.g.*, custody seals, records) during transfer from the field to the laboratory, in the laboratory, and among contractors and subcontractors shall be described to ensure that sample integrity is maintained.

4.16 Sample archival requirements for each relevant organization shall be provided.

SECTION 5.0, TESTING AND MEASUREMENT PROTOCOLS

5.1 Each measurement method to be used shall be described in detail or referenced. Modifications to EPA_approved or similarly validated methods shall be specified.

5.2 For unproven methods, verification data applicable to expected matrices shall be included in the QAPP meaning the QAPP shall provide evidence that the proposed method is capable of achieving the desired performance.

5.3 For measurements which require a calibrated system, the QAPP shall include specific calibration procedures applicable to each project target analyte, and the procedures for verifying both initial and continuing calibrations (including frequency and acceptance criteria, and corrective actions to be performed if acceptance criteria are not met).

SECTION 6.0, QA/QC CHECKS

6.1 At a minimum, the QAPP shall include quantitative acceptance criteria for QA objectives associated with accuracy, precision, detection limits, and completeness for critical measurements (process, physical, and analytical, as applicable) for each matrix.

6.2 Any additional project-specific QA objectives shall be presented, including acceptance criteria. This includes items such as mass balance requirements.

6.3 The specific procedures used to assess all identified QA objectives shall be fully described.

6.4 The QAPP shall list and define all other QC checks and/or procedures (*e.g.*, blanks, surrogates, controls, *etc.*) used for the project, both field and laboratory.

6.5 For each specified QC check or procedure, required frequencies, associated acceptance criteria, and corrective actions to be performed if acceptance criteria are not met shall be included.

SECTION 7.0, DATA REPORTING, DATA REDUCTION, AND DATA VALIDATION

7.1 The reporting requirements (*e.g.*, units, reporting method [wet or dry]) for each measurement and matrix shall be identified.

7.2 The deliverables expected from each organization responsible for field and laboratory activities shall be listed.

7.3 Data reduction procedures specific to the project, and also specific to each organization, shall be summarized.

7.4 Data validation procedures specific to each organization used to ensure the reporting of accurate project data to internal and external clients shall be summarized.

7.5 Data storage requirements for each organization shall be provided.

7.6 The product document that will be prepared for the project shall be specified (*e.g.*, journal article, final report, *etc.*). The contents of this document can be referenced to a NHSRC or program-specific QMP, if appropriate.

SECTION 8.0, ASSESSMENTS

8.1 The QAPP shall identify all scheduled audits (*i.e.*, both technical system audits [TSAs] and performance evaluations [PEs]) to be performed, who will perform these audits, and who will receive the audit reports.

8.2 The QAPP shall provide procedures that are to be followed that will ensure that necessary corrective actions will be performed.

8.3 The responsible party(-ies) for implementing corrective actions shall be identified.

SECTION 9.0, REFERENCES

References shall be provided either in the body of the text as footnotes or in a separate section.

Attachment # 2

NHSRC QA

To the Statement of Work
Requirements/Definitions List

EPAs Quality System Website: http://www.epa.gov/quality
EPA's Requirements and Guidance Documents: http://www.epa.gov/quality/qa_docs.html
EPA's Quality System Website: http://www.epa.gov/quality/qs-docs/r5-final.pdf

In accordance with EPA Order 5360.1 A2, conformance to ANSI/ASQC E4 must be demonstrated by submitting the quality documentation described herein. All Quality documentation shall be submitted to the Government for review. The Government will review and return the quality documentation, with comments, and indicate approval or disapproval. If the quality documentation is not approved, it must be revised to address all comments and shall be resubmitted to the Government for approval. Work involving environmental data collection, generation, use, or reporting shall not commence until the Government has approve the quality documentation. The Quality Assurance Project Plan (QAPP) shall be submitted to the Government at least thirty (30) days prior to the beginning of any environmental data gathering or generation activity in order to allow sufficient time for review and revisions to be completed. After the Government has approved the quality documentation, the Contractor shall also implement it as written and approved by the Government.

NHSRC's Quality System Specifications for Extramural Actions –

These requirements typically pertain to single project efforts. The five specifications are:

(1) a description of the organization's Quality System (QS) and information regarding how this QS is documented, communicated and implemented;
(2) an organizational chart showing the position of the QA function;
(3) delineation of the authority and responsibilities of the QA function;
(4) the background and experience of the QA personnel who will be assigned to the project; and
(5) the organization's general approach for accomplishing the QA specifications in the SOW.

NHSRC QA Requirements/Definitions List
Category Level Designations (determines the level of QA required):

☐ **Category I Project** - applicable to studies performed to generate data used for enforcement activities, litigation, or research project involving human subjects. The QAPP shall address all elements listed in "EPA Requirements for QA Project Plans, EPA QA/R-5.

☐ **Category II Project** - applicable to studies performed to generate data used in support of the development of environmental regulations or standards. The QAPP shall address all elements listed in "EPA Requirements for QA Project Plans, EPA QA/R-5.

☐ **Category III Project** - applicable to projects involving applied research or technology evaluations. The QAPP shall address the applicable sections of "EPA Requirements for QA Project Plans, EPA QA/R-5 as outlined in the NHSRC's QMP: QAPP requirements for the specific project type (see below).

☐ **Category IV Project** - applicable to projects involving basic research or preliminary data gathering activities. The QAPP shall address the applicable sections of "EPA Requirements for QA Project Plans, EPA QA/R-5 as outlined in the NHSRC's QMP QAPP requirements for the specific project type (see below).

Project Types:

These outlines of NHSRC's QAPP Requirements for various project types, from Appendix B of the NHSRC QMP (except where otherwise noted), are condensed from typically applicable sections of R-5 (EPA Requirements for QA Project Plans) and are intended to serve as a starting point when preparing a QAPP. These lists and their format may not fit every research scenario and QAPP's must conform to applicable sections of R-5 in a way that fully describes the research plan and appropriate QA and QC measures to ensure that the data are of adequate quality and quantity to fit their intended purpose.

☐ **Applied Research Project** - pertains to a study performed to generate data to demonstrate the performance of accepted processes or technologies under defined conditions. These studies are often pilot- or field-scale. The QAPP shall address all requirements listed in "QAPP Requirements for Applied Research Projects" from Appendix B of the NHSRC QMP.

☐ **Basic Research Project** - pertains to a study performed to generate data used to evaluate unproven theories, processes, or technologies. These studies are often bench-scale. The QAPP shall address all requirements listed in "QAPP Requirements for Basic Research Projects" from Appendix B of the NHSRC QMP.

☐ **Design, Construction, and/or Operation of Environmental Technology Project** - pertains to environmental technology designed, constructed and/or operated by and/or for EPA. The QAPP shall address requirements in the EPA Quality System document "Guidance on Quality Assurance for Environmental Technology Design, Construction, and Operation" G-11, at http://www.epa.gov/quality/QS-docs/g11-final-06.pdf. For additional information, you may refer to Part C of "Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology," ANSI/ASQC E4-1994, American Society for Quality Control, Milwaukee, WI, January 1995.

☐ **Geospatial Data Quality Assurance Project** - pertains to data collection; data processing and analysis; and data validation of geospatial applications. The QAPP shall address requirements in the EPA Quality System document "Guidance for Geospatial Data Quality Assurance Project Plans" G-5S at http://www.epa.gov/quality/QS-docs/g5s-final-05.pdf.

☐ **Method Development Project** - pertains to situations where there is no existing standard method, or a standard method needs to be significantly modified for a specific application. The QAPP shall address all requirements listed in "QAPP Requirements for Method Development Projects" from Appendix B of the NHSRC QMP.

☐ **Model Development Project** - includes all types of mathematical models including static, dynamic, deterministic, stochastic, mechanistic, empirical, etc. The QAPP shall address requirements in the EPA Quality System document "Guidance for Quality Assurance Project Plans for Modeling" G-5M at http://www.epa.gov/quality/QS-docs/g5m-final.pdf.

☐ **Sampling and Analysis Project** - pertains to the collection and analysis of samples with no objectives other than to provide characterization or monitoring information. The QAPP shall address all requirements listed in "QAPP Requirements for Sampling and Analysis Projects" from Appendix B of the NHSRC QMP.

☐ **Secondary Data Project** - pertains to environmental data collected from other sources, by or for EPA, that are used for purposes other than those originally intended. Sources may include: literature, industry surveys, compilations from computerized databases and information systems, and computerized or mathematical models of environmental processes. The QAPP shall address all requirements listed in "QAPP Requirements for Secondary Data Projects" from Appendix B of the NHSRC QMP.

☐ **Software Development and Data Management Project** - pertains to software development, software/hardware systems development, database design and maintenance, data validation and verification systems. The QAPP shall address all requirements listed in "QAPP Requirements for Software Development Projects" from Appendix B of the NHSRC QMP.

Definitions:

Environmental Data - These are any measurement or information that describe environmental processes, location, or conditions; ecological or health effects directly from measurements, produced from software and models, and compiled from other sources such as data bases or the literature. For EPA, environmental data include information collected directly from measurements, produced from software and models, and compiled from other sources such as data bases or literature.

Incremental Funding - Incremental funding is partial funding, no new work.

Quality Assurance (QA) - Quality assurance is a system of management activities to ensure that a process, item, or service is of the type and quality needed by the customer. It deals with setting policy and running an administrative system of management controls that cover planning, implementation, and review of data collection activities and the use of data in decision making. Quality assurance is just one part of a quality system.

Quality Assurance Project Plan (QAPP) - A QAPP is a document that describes the necessary quality assurance, quality control, and other technical activities that must be implemented to ensure that the results of the work performed will satisfy the stated performance criteria. A QAPP documents project-specific information.

Quality Control (QC) - Quality control is a technical function that includes all the scientific precautions, such as calibrations and duplications, which are needed to acquire data of known and adequate quality.

Quality Management Plan (QMP) - A QMP is a document that describes an organization's/program's quality system in terms of the organizational structure, policy and procedures, functional responsibilities of management and staff, lines of authority, and required interfaces for those planning, implementing, documenting, and assessing all activities conducted. A QMP documents the overall organization/program, and is primarily applicable to multi-year, multi-project efforts. An organization's/program's QMP shall address all elements listed in the "Requirements for Quality Management Plans" in Appendix B of the NHSRC QMP.

Quality System - A quality system is the means by which an organization manages its quality aspects in a systematic, organized manner and provides a framework for planning, implementing, and assessing work performed by an organization and for carrying out required quality assurance and quality control activities.

R-2. EPA Requirements for Quality Management Plans (EPA/240/B-01/002) March, 2001 http://www.epa.gov/quality/QS-docs/r2-final.pdf.

R-5. EPA Requirements for Quality Management Plans (EPA/240/B-01/002) March, 2001 http://www.epa.gov/quality/QS-docs/r5-final.pdf.

Substantive Change - Substantive change is any change in an activity that may alter the quality of data being used, generated, or gathered.

Technical Lead Person (TLP) - This person is technically responsible for the project. For extramural contract work, the TLP is typically the contracting officer's representative (COR). For intramural work, the TLP is typically the Principal Investigator.

Abbreviations:

COR	Contracting Officer's Representative	IAG	Interagency Agreement
NHSRC	National Homeland Security Research Center	QA	Quality Assurance
NRMRL	National Risk Management Research Laboratory	QAM	Quality Assurance Manager
QA ID	Quality Assurance Identification	QMP	Quality Management Plan
QAPP	Quality Assurance Project Plan	SOW	Statement of Work
QS	Quality System	CRADA	Cooperative Research & Development Agreement
TLP	Technical Lead Person		

SURVEILLANCE PLAN
FOR PERSISTENCE OF VEGETATIVE BACILLUS ANTHRACIS AND YERSINIA PESTIS

TASK ORDER PR-ORD-12-01943

Performance Objective (Task)	Performance Standard (PS)	Surveillance Plan (SP)	Contractor Incentive (CI)	✓ or X
Task 1: Quality assurance plan.	Contractor drafts a quality assurance plan and revises as directed by TOCOR and EPA's quality assurance (QA) manager.	TOCOR and the EPA QA manager will review the quality assurance plan.	TOCOR will address compliance in PPE	x
Task 2: Perform persistence tests.	Contractor conducts all tests outlined in the SOW and QAPP. Data are delivered to TOCOR(for example, but not limited to, raw data, agent recoveries, data quality indicators, temperature and relative humidity levels) periodically as indicated in SOW.	TOCOR will document whether receipt of data delivery is complete and timely.	TOCOR will address compliance in PPE	x
Task 3: Report.	Contractor completes 3 drafts of the report. Contractor addresses TOCOR QA and peer review comments, as outlined in SOW.	TOCOR will provide comments on final report and document that the contractor has addressed all the TOCOR, QA and peer review comments.	TOCOR will address compliance in PPE	x